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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet 1 of 3

Complete if Known

Application Number	09/580,015
Filing Date	05/26/00
First Named Inventor	Dale B. Schenk
Group Art Unit	1641
Examiner Name	Unassigned
Attorney Docket Number	15270J-004750US

## **U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	196	6,150,091		Pandolfo et al.	11-21-2000	
	1	6,057,367		Stamler et al.	05-02-2000	
	207	5,780,587		Potter	07-14-1998	
	197	5,744,368		Goldgaber et al.	04-28-1998	
	211	5,736,142		Sette et al.	04-07-1998	
	175	5,441,870		Seubert, et al.	08-15-1995	
	181	5,270,165		Van Nostrand et al.	12-14-1993	
	32	5,187,153		Cordell et al.	02-16-93	
	198	5,004,697		Pardridge	04-0201991	

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	187	EP	783 104	A1		07-09-1997		<input type="checkbox"/>
	199	PCT	00/77178	A1		12-21-2000		<input type="checkbox"/>
	188	PCT	00/43049	A1		07-27-2000		<input type="checkbox"/>
	203	PCT	99/00150	A2		01-07-1999		<input type="checkbox"/>
	202	PCT	97/21728	A1		06-19-1997		<input type="checkbox"/>
	208	PCT	96/28471	A1		09-19-1996		<input type="checkbox"/>
	200	PCT	95/12815	A1		05-11-1995		<input type="checkbox"/>
	201	PCT	94/28412	A1		12-08-1994		<input type="checkbox"/>
	205	PCT	93/04194	A1		03-04-1993		<input type="checkbox"/>
	87	PCT	89/01343	A1		02-23-1989		<input type="checkbox"/>

Examiner Signature

Date Considered

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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language translation is attached.

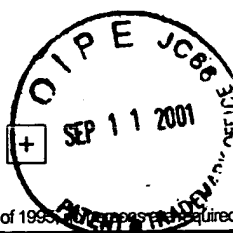
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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet 2 of 3

## **Complete if Known**

Application Number	09/580,015
Filing Date	05/26/00
First Named Inventor	Dale B. Schenk
Group Art Unit	1641
Examiner Name	Unassigned
Attorney Docket Number	15270J-004750US

## **OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	204	BERCOVICI et al., "Chronic Intravenous Injections of Antigen Induce and Maintain Tolerance in T Cell Receptor-Transgenic Mice," <u>Eur. J. Immunol.</u> 29:345-354 (1999).	<input type="checkbox"/>
	212	BICKEL et al., "Site Protected, Cationized Monoclonal Antibody Against Beta Amyloid as a Potential Diagnostic Imaging Technique for Alzheimer's Diseases," <u>Soc. for Neuroscience Abstracts</u> 18:764 (1992).	<input type="checkbox"/>
	176	BARD et al., "Peripherally administered antibodies against amyloid $\beta$ -peptide enter the central nervous system and reduce pathology in a mouse model of Alzheimer disease," <u>Nature Medicine</u> , 6(8):916-919 (2000).	<input type="checkbox"/>
	213	CHEN et al. "An Antibody to $\beta$ Amyloid Precursor Protein Inhibits Cell-substratum Adhesion in Many Mammalian Cell Types," <u>Neuroscience Letters</u> 125:223-226 (1991).	<input type="checkbox"/>
	214	DEMATOS et al., "Peripheral Anti A $\beta$ Antibody Alters CNS And Plasma A $\beta$ Clearance and Decreases Brain A $\beta$ Burden in a Mouse Model of Alzheimer's Disease," <u>Proc. Natl. Acad. Sci. USA</u> , 10.1073/pnas.151261398 (2001).	<input type="checkbox"/>
	210	FRIEDLAND et al., "Development of an anti-A $\beta$ monoclonal antibody for in vivo imaging of amyloid angiopathy in Alzheimer's disease," <u>Mol. Neurology</u> , 9:107-113 (1994).	<input type="checkbox"/>
	215	GAMES et al., "Prevention and Reduction of AD-type Pathology in PDAPP Mice Immunized with A $\beta$ <sub>1-42</sub> ," <u>Annals of the New York Academy of Science</u> 920:274-84 (2000).	<input type="checkbox"/>
	190	GRAVINA et al., "Amyloid $\beta$ Protein (A $\beta$ ) in Alzheimer's Disease," <u>J. Biol. Chem.</u> , 270(13):7013-7016 (1995).	<input type="checkbox"/>
	193	HARRINGTON et al., "Characterisation of an epitope specific to the neuron-specific isoform of human enolase recognised by a monoclonal antibody raised against a synthetic peptide corresponding to the C-terminus of $\beta$ / A4-protein," <u>Biochimica Biophysica Acta</u> , 1158:120-128 (1993).	<input type="checkbox"/>
	177	HELMUTH, L., "Further Progress on a $\beta$ -Amyloid Vaccine," <u>Science</u> , 289:375 (2000).	<input type="checkbox"/>
	192	IWATSUBO et al., "Visualization of A $\beta$ 42(43) and A $\beta$ 40 in Senile Plaques with End-Specific A $\beta$ Monoclonals: Evidence That an Initially Deposited Species Is A $\beta$ 42(43)," <u>Neuron</u> , 13:45-53 (1994).	<input type="checkbox"/>
	216	JOACHIM et al., "Antibodies to Non-beta Regions of the Beta-amyloid Precursor Protein Detect a Subset of Senile Plaques," <u>Am. J. of Pathology</u> 138:373-378 (1991).	<input type="checkbox"/>
	183	KATZAV-GOZANSKY et al., "Effect of monoclonal antibodies in preventing carboxypeptidase A aggregation," <u>Biotechnol. Appl. Biochem.</u> , 23:227-230 (1996).	<input type="checkbox"/>
	195	KONIG et al., "Development and Characterization of a Monoclonal Antibody 369.2B Specific for the Carboxyl-Terminus of the $\beta$ A4 Peptide," <u>Annals of NY Acad. Sci.</u> , 777:344-355 (1996).	<input type="checkbox"/>
	218	MAJOCHA et al., "Development of a Monoclonal Antibody Specific for $\beta$ /A4 Amyloid in Alzheimer's Disease Brain for Application to In Vitro Imaging of Amyloid Angiopathy," <u>The J. of Nuclear Med.</u> 33:2184-2189 (1992).	<input type="checkbox"/>

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Date Considered

10-7-02

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Sheet 3 of 3

Complete if Known

Application Number 09/580,015  
Filing Date 05/26/00  
First Named Inventor Dale B. Schenk  
Group Art Unit 1641  
Examiner Name Unassigned  
Attorney Docket Number 15270J-004750US

217	MASTERS et al., "Amyloid Plaque core protein in Alzheimer Disease and Down Syndrome," <u>Proc. Natl. Acad. Sci. USA</u> , 82:4245-4249 (1985).	<input type="checkbox"/>
206	MORI et al., "Mass Spectrometry of Purified Amyloid $\beta$ Protein in Alzheimer's Disease," <u>J. Biol. Chem.</u> , 267(24):17082-17088 (1992).	<input type="checkbox"/>
191	MURPHY et al., "Development of a Monoclonal Antibody Specific for the COOH-Terminal of $\beta$ -Amyloid 1-42 and Its Immunohistochemical Reactivity in Alzheimer's Disease and Related Disorders," <u>Am. J. Pathology</u> , 144(5):1082-1088 (1994).	<input type="checkbox"/>
144	RASO, V.A., Grant application # 1 R43 AGI 5746-01, (publication date unknown).	<input type="checkbox"/>
209	RUDINGER, "Characteristics of the Amino Acids as Components of a Peptide Hormone Sequence," in <u>Peptide Hormones</u> , J.A. Parson, ed. University Park Press, Baltimore, pp 1-7 (1976).	<input type="checkbox"/>
189	SAIDO et al., "Spatial Resolution of Fodrin Proteolysis in Postischemic Brain," <u>J. Biol. Chem.</u> , 268(33):25239-25243 (1993).	<input type="checkbox"/>
194	SAIDO et al., "Spatial Resolution of the Primary $\beta$ -Amyloidogenic Process Induced in Postischemic Hippocampus," <u>J. Biol. Chem.</u> , 269(21):15253-15257 (1994).	<input type="checkbox"/>
178	SCHENK et al., "Therapeutic Approaches Related to Amyloid- $\beta$ Peptide and Alzheimer's Disease," <u>J. Med. Chem.</u> , 38(21):4141-4154 (1995).	<input type="checkbox"/>
182	SOLOMON et al., "Inhibitory effect of monoclonal antibodies on Alzheimer's $\beta$ -amyloid peptide aggregation," <u>Int. J. Exp. Clin. Invest.</u> , 3:130-133 (1996).	<input type="checkbox"/>
184	SOLOMON et al., "Thermal Stabilization of Carboxypeptidase A as a Function of PH and Ionic Milieu," <u>Biochem. Mol. Biol. Int.</u> , 43(3):601-611 (1997).	<input type="checkbox"/>
185	SOLOMON et al., "Modulation of The Catalytic Pathway of Carboxypeptidase A by Conjugation with Polyvinyl Alcohols," <u>Adv. Mol. Cell Biology</u> , 15A:33-45 (1996).	<input type="checkbox"/>
186	SOLOMON et al., "Activity of monoclonal antibodies in prevention of in vitro aggregation of their antigens," abstract from Department of Molecular Microbiology and Biotechnology, Tel Aviv University, Tel Aviv, Israel (publication date unknown).	<input type="checkbox"/>
179	SOUTHWICK et al., "Assessment of Amyloid $\beta$ protein in Cerebrospinal fluid as an Aid in the Diagnosis of Alzheimer's Disease," <u>J. Neurochemistry</u> , 66:259-265 (1996).	<input type="checkbox"/>
180	WEN, G.Y., "Alzheimer's Disease and Risk Factors," <u>J. Food Drug Analysis</u> , 6(2):465-476 (1998).	<input type="checkbox"/>
219	WONG et al., "Neuritic Plaques and Cerebrovascular Amyloid in Alzheimer Disease are Antigenically Related," <u>Proc. Natl. Acad. Sci. USA</u> , 82:8729-8732 (1985).	<input type="checkbox"/>

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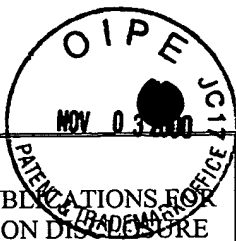
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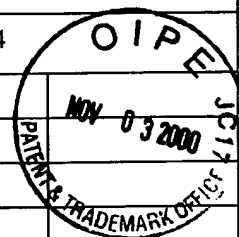


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FORM PTO-1449 (Modified)			Attorney Docket No.: 15270J-004750US		Application No.: 09/580,015	
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)			Applicant: Dale Schenk et al.		Filing Date: May 26, 2000	
			Group: 1614			
Reference Designation			U.S. PATENT DOCUMENTS			Page 1
Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date (If Appropriate)
AA	5,958,883	9/28/99	Snow			
AB	5,955,317	9/21/99	Suzuki et al.			
AC	5,955,079	9/21/99	Mond et al.			
AD	5,877,399	3/2/99	Hsiao et al.			
AE	5,869,093	2/9/99	Weiner et al.			
AF	5,869,054	2/9/99	Weiner et al.			
AG	5,854,204	12/29/98	Findeis et al.			
AH	5,851,996	12/22/98	Kline			
AI	5,849,298	12/15/98	Weiner et al.			
AJ	5,837,473	11/17/98	Maggio et al.			
AK	5,786,180	7/28/98	Konig et al.			
AL	5,753,624	5/19/98	McMichael et al.			
AM	5,750,349	5/12/98	Suzuki et al.			
AN	5,733,547	3/31/98	Weiner et al.			
AO	5,688,651	11/18/97	Solomon			
AP	5,679,348	10/21/97	Nesburn et al.			
AQ	5,645,820	7/8/97	Hafler et al.			
AR	5,641,474	6/24/97	Hafler et al.			
AS	5,641,473	6/24/97	Hafler et al.			
AT	5,612,486	3/18/97	McConlogue et al.			
AU	5,605,811	2/25/97	Seubert et al.			
AV	5,585,100	12/17/96	Mond et al.			
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AY	5,434,170	7/18/95	Andrulis et al.			
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BA	5,231,000	7/27/93	Majocha et al.			
BB	5,220,013	6/15/93	Ponte et al.			
BC	5,208,036	5/4/93	Eppstein et al.			
BD	5,192,753	3/9/93	McGeer et al.			
BE	5,057,540	10/15/91	Kensil et al.			
BF	4,666,829	5/19/85	Glennner er al.			
FOREIGN PATENT DOCUMENTS						
	Document No.	Date	Country	Class	Sub-class	Translation (Yes/No)
BG	WO 99/60024	11/25/99	PCT			

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FORM PTO-1449 (Modified)			Attorney Docket No.: 15270J-004750US		Application No.: 09/580,015	
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)			Applicant: Dale Schenk et al.		Group: 1614	
			Filing Date: May 26, 2000			
BH	WO 99/60021	11/25/99	PCT			
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BM	WO 99/06066	2/11/99	PCT			
BN	WO 98/44955	10/15/98	PCT			
BO	WO 98/07850	2/26/98	PCT			
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BQ	WO 96/39176	12/12/96	PCT			
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CD	WO 93/02189	2/4/93	PCT			
CE	WO 92/13069	8/6/92	PCT			
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CG	WO 92/06187	4/16/92	PCT			
CH	WO 91/16819	11/14/91	PCT			
CI	WO 91/19810	12/26/91	PCT			
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CK	WO 91/08760	6/27/91	PCT			
CL	WO 90/12871	11/1/90	PCT			
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CP	WO 89/03687	5/5/89	PCT			
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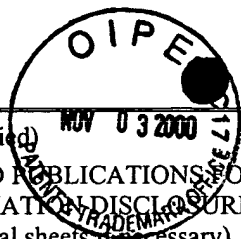


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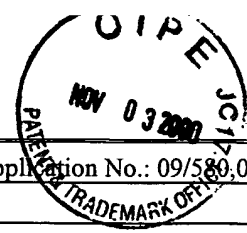
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FORM PTO-1449 (Modified)			Attorney Docket No.: 15270J-004750US		Application No. 09/588,915	
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)			Applicant: Dale Schenk et al.		Group: 614 NOV 03 2000	
			Filing Date: May 26, 2000			
CT	EP 561 087	8/4/99	Europe			
CU	EP 526 511	5/28/97	Europe			
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CW	EP 652 962	12/16/98	Europe			
CX	EP 868 918	10/7/98	Europe			
CY	EP 863 211	9/9/98	Europe			
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DA	EP 594 607	8/27/97	Europe			
DB	EP 782 859	7/9/97	Europe			
DC	EP 440 619	1/24/96	Europe			
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DE	EP 683 234	11/22/95	Europe			
DF	EP 666 080	8/9/95	Europe			
DG	EP 451 700	10/16/91	Europe			
DH	EP 276 723	12/8/93	Europe			Yes
DI	GB 2 335 192	9/15/99	United Kingdom			
DJ	GB 2 220 211	1/4/90	United Kingdom			
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>						
DK	Andersen et al., "Do nonsteroidal anti-inflammatory drugs decrease the risk for Alzheimer's disease?," <u>Neurology</u> , 45:1441-1445 (1995).					
DL	Associated Press, "Immune cells may promote Alzheimer's, a study finds," <u>The Boston Globe</u> (4/13/95).					
DM	Bauer et al., "Interleukin-6 and $\alpha$ -2-macroglobulin indicate an acute-phase state in Alzheimer's disease cortices," <u>FEBS Letters</u> , 285(1):111-114 (1991).					
DN	Blass, John P., "Immunologic Treatment of Alzheimer's Disease," <u>New England J. Medicine</u> , 341(22):1694 (1999).					
DO	Bodmer et al., "Transforming Growth Factor-Beta Bound to Soluble Derivatives of the Beta Amyloid Precursor Protein of Alzheimer's Disease," <u>Biochem. Biophys. Res. Comm.</u> , 171(2):890-897 (1990).					
DP	Borchelt et al., "Accelerated Amyloid Deposition in the Brains of Transgenic Mice Coexpressing Mutant Presenilin 1 and Amyloid Precursor Proteins," <u>Neuron</u> , 19: 939-945 (1997).					
DQ	Boris-Lawrie et al., "Recent advances in retrovirus vector technology," <u>Cur. Opin. Genet Develop.</u> , 3: 102-109 (1993).					
DR	Brice et al., "Absence of the amyloid precursor protein gene mutation (APP717 : Val->Ile) in 85 cases of early onset Alzheimer's disease," <u>J. Neurology, Neurosurg. Psychiatry</u> , 56:112-115 (1993).					
DS	Chao et al., "Transforming Growth Factor- $\beta$ Protects human Neurons Against $\beta$ -Amyloid-Induced Injury," <u>Soc. Neurosci. Abstracts</u> , 19:513.7 (1993).					
DT	Duff et al., "Mouse model made," <u>Nature</u> , 373: 476-477 (1995)					
DU	Elizan et al., "Antineurofilament antibodies in a postencephalitic and idiopathic parkinson's disease," <u>J. Neurol. Sciences</u> , 59:341-347 (1983).					
DV	Felsenstein et al., "Processing of the $\beta$ -amyloid precursor protein carrying the familial, Dutch-type, and a novel recombinant C-terminal mutation," <u>Neuroscience Letters</u> , 152:185-189 (1993).					
DW	Finch et al., "Evolutionary Perspectives on Amyloid and Inflammatory Features of Alzheimer Disease," <u>Neurobiology of Aging</u> , 17(5):809-815 (1996).					

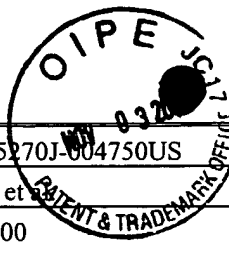


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		Filing Date: May 26, 2000	Group: 1614
<u>8</u> DX	Fisher et al., "Expression of the amyloid precursor protein gene in mouse oocytes and embryos," <u>PNAS</u> , 88:1779-1782 (1991).		
<u>8</u> DY	Flanders et al., "Altered expression of transforming growth factor- $\beta$ in Alzheimer's disease," <u>Neurology</u> , 45:1561-1569 (1995).		
<u>8</u> DZ	Games et al., "Alzheimer-type neuropathology in transgenic mice overexpressing V717F $\beta$ -amyloid precursor protein", <u>Nature</u> , 373(6514): 523-527 (1995).		
<u>8</u> EA	Gandy et al., "Amyloidogenesis in Alzheimer's disease: some possible therapeutic opportunities," <u>TIPS</u> , 13:108-113 (1992).		
<u>8</u> EB	Gaskin et al., "Human antibodies reactive with beta-amyloid protein in Alzheimer's disease," <u>J. Exp. Med.</u> , 177:1181-1186 (1993).		
<u>8</u> EC	Glenn et al., "Skin immunization made possible by cholera toxin", <u>Nature</u> , 391: 851 (1998).		
<u>8</u> ED	Glenner et al., "Alzheimer's Disease: Initial Report of the Purification and Characterization of a Novel Cerebrovascular Amyloid Protein", <u>Biochemical and Biophysical Research Communications</u> , 120(3): 885-890 (1994).		
<u>8</u> EE	Glenner et al., "Alzheimer's Disease and Downs Syndrome: Sharing of A Unique Cerebrovascular Amyloid Fibril Protein", <u>Biochemical and Biophysical Research Communications</u> , 122(3): 1131-1135 (1984).		
<u>8</u> EF	Goate et al., "Segregation of a missense mutation in the amyloid precursor protein gene with familial Alzheimer's disease," <u>Nature</u> , 349:704-706 (1991).		
<u>8</u> EG	Gozes et al., "Neuroprotective strategy for Alzheimer disease: Intranasal administration of a fatty neuropeptide," <u>PNAS</u> , 93:427-432 (1996).		
<u>8</u> EH	Gupta et al., "Differences in the immunogenicity of native and formalized cross reacting material (CRM197) of diphtheria toxin in mice and guinea pigs and their implications on the development and control of diphtheria vaccine based on CRMs", <u>Vaccine</u> , 15(12/13): 1341-1343 (1997).		
<u>8</u> EI	Haga et al., "Synthetic Alzheimer amyloid $\beta$ /A4 peptides enhance production of complement C3 component by cultured microglial cells," <u>Brain Research</u> , 601:88-94 (1993).		
<u>8</u> EJ	Hanes et al., "New advances in microsphere-based single-dose vaccines", <u>Advanced Drug Delivery Reviews</u> , 28: 97-119 (1997).		
<u>8</u> EK	Hardy, "Amyloid, the presenilins and Alzheimer's disease", <u>TINS</u> , 20(4): 154-159 (1997).		
<u>8</u> EL	Hardy, John, "New Insights into the Genetics of Alzheimer's Disease," <u>Annals of Med.</u> , 28:255-258 (1996).		
<u>8</u> EM	Hsiao et al., "Correlative Memory Deficits, A $\beta$ Elevation, and Amyloid Plaques in Transgenic Mice", <u>Science</u> , 274: 99-102 (1996).		
<u>8</u> EN	Huberman et al., "Correlation of cytokine secretion by mononuclear cells of Alzheimer's patients and their disease stage," <u>J. Neuroimmunology</u> , 52:147-152 (1994).		
<u>8</u> EO	Hyman et al., "Molecular Epidemiology of Alzheimer's Disease," <u>N. E. J. Medicine</u> , 333(19):1283-1284 (1995).		
<u>8</u> EP	Itagaki et al., "Relationship of microglia and astrocytes to amyloid deposits of Alzheimer's disease," <u>J. Neuroimmunology</u> , 24:173-182 (1989).		
<u>8</u> EQ	Jansen et al., "Immunotoxins: Hybrid Molecules Combining High Specificity and Potent Cytotoxicity", <u>Immun. Rev.</u> , 62: 185-216 (1982).		
<u>8</u> ER	Kalaria, R. N., "Serum amyloid P and related molecules associated with the acute-phase response in Alzheimer's disease," <u>Res. Immunology</u> , 143:637-641 (1992).		
<u>8</u> ES	Kawabata et al., "Amyloid plaques, neurofibrillary tangles and neuronal loss in brains of transgenic mice overexpressing a C-terminal fragment of human amyloid precursor protein," <u>Nature</u> , 354:476-478 (1991).		
<u>8</u> ET	Lampert-Etchells et al., "Regional Localization of Cells Containing Complement C1q and C4 mRNAs in the Frontal Cortex During Alzheimer's Disease," <u>Neurodegeneration</u> , 2:111-121 (1993).		
<u>8</u> EU	Langer, "New Methods of Drug Delivery", <u>Science</u> , 249: 1527-1532 (1990).		
<u>8</u> EV	Lannfelt et al., "Alzheimer's disease: molecular genetics and transgenic animal models," <u>Behavioural Brain Res.</u> , 57:207-213 (1993).		



FORM PTO-1449 (Modified)		Attorney Docket No.: 15270J-004750US	Application No.: 09/580,015
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: Dale Schenk et al.	
		Filing Date: May 26, 2000	
		Group: 1614	
<del>8</del> EW	Lemere et al., "Mucosal Administration of A $\beta$ Peptide Decreases Cerebral Amyloid Burden In Pd-App Transgenic Mice," <u>Society for Neuroscience Abstracts</u> , vol. 25, part I, Abstract 519.6, 29th Annual Meeting, 10/23-28/99.		
<del>8</del> EX	Livingston et al., "The Hepatitis B Virus-Specific CTL Responses Induced in Humans by Lipopeptide Vaccination Are Comparable to Those Elicited by Acute Viral Infection", <u>J. Immunol.</u> , 159: 1383-1392 (1997).		
<del>8</del> EY	Lopez et al., "Serum auto-antibodies in Alzheimer's disease," <u>Acta. Neurol. Scand.</u> , 84:441-444 (1991).		
<del>8</del> EZ	McGee et al., "The encapsulation of a model protein in poly (D, L lactide-co-glycolide) microparticles of various sizes: an evaluation of process reproducibility", <u>J. Micro. Encap.</u> , 14(2): 197-210 (1997).		
<del>8</del> FA	Meda et al., "Activation of microglial cells by $\beta$ -amyloid protein and interferon- $\gamma$ ," <u>Nature</u> , 374:647-650 (1995).		
<del>8</del> FB	Miller et al., "Antigen-driven Bystander Suppression after Oral Administration of Antigens," <u>J. Exp. Med.</u> , 174:791-798 (1991).		
<del>8</del> FC	Nathanson et al., "Bovine Spongiform Encephalopathy (BSE): Causes and Consequences of a Common Source Epidemic", <u>Am. J. Epidemiol.</u> , 145(11): 959-969 (June 1, 1997).		
<del>8</del> FD	New York Times National, "Anti-Inflammatory Drugs May Impede Alzheimer's," (2/20/94).		
<del>8</del> FE	Paresce et al., "Microglial cells influence aggregates of the Alzheimer's disease amyloid beta-protein via a scavenger receptor," <u>Neuron</u> , 17:553-565 (September 1996).		
<del>8</del> FF	Paul et al., "Transdermal immunization with large proteins by means of ultradeformable drug carriers", <u>Eur. J. Immunol.</u> , 25: 3521-3524 (1995).		
<del>8</del> FG	Prieels et al., "Synergistic adjuvants for vaccines", <u>Chemical Abstracts</u> , 120(8): pg. 652, column 1, abstract 86406t (1994).		
<del>8</del> FH	Quon et al., "Formation of $\beta$ -Amyloid protein deposits in brains of transgenic mice," <u>Nature</u> , 352:239-241 (1991).		
<del>8</del> FI	Raso, V. A., "Immunotherapy of Alzheimer's Disease," <u>Immunotherapy Weekly</u> , Abstract (4/2/98).		
<del>8</del> FJ	Rogers et al., "Complement activation by $\beta$ -amyloid in Alzheimer Disease," <u>PNAS</u> , 89:1-5 (1992).		
<del>8</del> FK	Rossor et al., "Alzheimer's Disease Families with Amyloid Precursor Protein Mutations," <u>Annals of New York Academy of Sciences</u> , 695:198-202 (1993).		
<del>8</del> FL	Selkoe, D.J., "Imaging Alzheimer's Amyloid," <u>Nat. Biotech.</u> , 18:823-824 (2000).		
<del>8</del> FM	Selkoe, Dennis J., "Amyloid Protein and Alzheimer's Disease.....," <u>Scientific American</u> , pgs. 68-78 (11/91).		
<del>8</del> FN	Selkoe, Dennis J., "In the Beginning....," <u>Nature</u> , 354:432-433 (1991).		
<del>8</del> FO	Selkoe, Dennis J., "The Molecular pathology of Alzheimer's Disease," <u>Neuron</u> , 6:487-498 (1991).		
<del>8</del> FP	Selkoe, Dennis J., "Alzheimer's Disease: Genotypes, Phenotype, and Treatments," <u>Science</u> , 275:630-631 (1997).		
<del>8</del> FQ	Selkoe, "Alzheimer's Disease: A Central Role for Amyloid", <u>J. Neuropathol. Exp. Neurol.</u> , 53(5): 438-447 (1994).		
<del>8</del> FR	Selkoe, "Physiological production of the $\beta$ -amyloid protein and the mechanism of Alzheimer's disease", <u>Trends in Neurosciences</u> , 16(10): 403-409 (1993).		
<del>8</del> FS	Seubert et al., "Isolation and quantification of soluble Alzheimer's $\beta$ -peptide from biological fluids", <u>Nature</u> , 359: 325-327 (1992).		
<del>8</del> FT	Shiosaka, Sadao, "Attempts to make models for Alzheimer's disease," <u>Neuroscience Res.</u> , 13:237-255 (1992).		
<del>8</del> FU	Smits et al., "Prion Protein and Scrapie Susceptibility", <u>Vet. Quart.</u> , 19(3): 101-105 (1997).		
<del>8</del> FV	Solomon et al., "Disaggregation of Alzheimer $\beta$ -amyloid by site-directed mAb," <u>PNAS</u> , 94:4109-4112 (1997).		
<del>8</del> FW	Solomon et al., "Monoclonal antibodies inhibit in <i>vitro</i> fibrillar aggregation of the Alzheimer $\beta$ -amyloid peptide," <u>PNAS</u> , 93:452-455 (1996).		
<del>8</del> FX	Solomon, A., "Pro-Rx (Protein Therapeutics)," University of Tennessee Medical Center.		
<del>8</del> FY	Solomon, B., "New Approach Towards Fast Induction of Anti $\beta$ -Amyloid Peptide Immune Response," Department of Molecular Microbiology & Biotechnology, Tel-Aviv University, ramat Aviv, Tel-Aviv, Israel.		
<del>8</del> FZ	Stoute et al., "A Preliminary Evaluation of a Recombinant Circumsporozoite Protein Vaccine Against <i>Plasmodium Falciparum</i> Malaria", <u>N. Engl. J. Med.</u> , 336(2): 86-91 (1997).		





FORM PTO-1449 (Modified)		Attorney Docket No.: 15270J-004750US	Application No.: 09/580,015
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: Dale Schenk et al.	
		Filing Date: May 26, 2000	Group: 1614
<del>80</del> GA	Sturchler-Pierrat et al., "Two amyloid precursor protein transgenic mouse models with Alzheimer disease-like pathology", <u>PNAS</u> , 94: 13287-13292 (1997).		
<del>81</del> GB	Tanaka et al., "NC-1900, an active fragment analog of arginine vasopressin, improves learning and memory deficits induced by beta-amyloid protein in rats," <u>European J. Pharmacology</u> , 352:135-142 (1998).		
<del>82</del> GC	Trieb et al., "Is Alzheimer beta amyloid precursor protein (APP) an autoantigen? Peptides corresponding to parts of the APP sequence stimulate T lymphocytes in normals, but not in patients with Alzheimer's disease," <u>Immunobiology</u> , 191(2-3):114-115 Abstract C.37, (1994).		
<del>83</del> GD	Verbeek et al., "Accumulation of Intercellular Adhesion Molecule-1 in Senile Plaques in Brain Tissue of patients with Alzheimer's Disease," <u>Amer. Journ. Pathology</u> , 144(1):104-116 (1994).		
<del>84</del> GE	Walker et al., "Labeling of Cerebral Amyloid <i>In Vivo</i> with a Monoclonal Antibody," <u>J. Neuropath. Exp. Neurology</u> , 53(4):377-383 (1994).		
<del>85</del> GF	Wengenack et al., "Targeting Alzheimer amyloid plaques in vivo," <u>Nature Biotech.</u> , 18:868-824 (2000).		
<del>86</del> GG	Weiner et al., "ORAL TOLERANCE: Immunologic Mechanisms and Treatment of Animal and Human Organ-Specific Autoimmune Diseases by Oral Administration of Autoantigens," <u>Annu. Rev. Immunol.</u> , 12:809-837 (1994).		
<del>87</del> GH	Weissmann et al., "Bovine spongiform encephalopathy and early onset variant Creutzfeldt-Jakob disease", <u>Curr. Opin. Neurobiol.</u> , 7: 695-700 (1997).		
<del>88</del> GI	Wood et al., "Amyloid precursor protein processing and A $\beta$ 42 deposition in a transgenic mouse model of Alzheimer disease", <u>PNAS</u> , 94: 1550-1555 (1997).		
<del>89</del> GJ	Human Immunology & Cancer Program brochure, from The University of Tennessee Medical Center/ Graduate School of Medicine, Knoxville, Tennessee.		
EXAMINER <u>Schenk</u> DATE CONSIDERED <u>10-7-02</u>			

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Sheet 1 of 6

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Application Number 09/580,015  
Filing Date May 26, 2000  
First Named Inventor Dale B. Schenk  
Group Art Unit 1647  
Examiner Name Turner, Sharon L.  
Attorney Docket Number 15270J-004750US

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## **U.S. PATENT DOCUMENTS**

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		Number	Kind Code <sup>2</sup> (if known)			
	221	5,989,566		Cobb et al.	11-23-1999	
	230	6,262,335	B1	Hsiao et al.	07-17-2001	
	231	6,114,133		Seubert et al.	09-05-2000	
	234	6,284,221	B1	Schenk, et al.	09-04-2001	
	242	60/168,594		Chalifour et al.	N/A	
	267	6,294,171	B2	McMichael	09-25-2001	
	282	60/169,687		Chain	N/A	
	283	09/441,140		Solomon et al.	11-16-1999	
	284	5,231,170		Averback	07-27-1993	
	295	60/184,601		Holtzman et al.	N/A	
	296	60/254,465		Holtzman et al.	N/A	
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	299	60/186,295		Rasmussen et al.	N/A	
	300	2001/0018053	A1	McMichael	08-30-2001	

## **FOREIGN PATENT DOCUMENTS**

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	227	PCT	95/11008	A2		04-27-1995		
	240	PCT	00/43039	A1		07-27-2000		
	243	PCT	01/39796	A2		06-07-2001		
	294	PCT	01/62801	A2		08-30-2001		
	298	PCT	01/42306	A2		06-14-2001		
	301	PCT	01/62284	A2		03-01-2000		

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Sheet	2	of	6	Application Number	09/580,015
				Filing Date	May 26, 2002
				First Named Inventor	Dale B. Schenk
				Group Art Unit	1647
				Examiner Name	Turner, Sharon L.
				Attorney Docket Number	15270J-004750US

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JS	228	BARROW, et al., "Solution Conformations and aggregational Properties of Synthetic Amyloid Beta-Peptides of Alzheimer's Disease. Analysis of Circular Dichroism Spectra" <u>J. Mol. Biol.</u> , 225(4): 1075-1093 (1992).		
JS	239	BEASLEY, "Alzheimer's traced to proteins caused by aging," Reuters, April 20, 2001 7:56 PM ET.		
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JS	266	CHAPMAN, PAUL F., "Model behavior," <u>Nature</u> , 408:915-916 (2000).		
X	222	Chemical Abstract database, Abstract of "Injection of Newborn Mice with Seven Chemical Adjuvants to Help Determine Their Safety in Use in Biologicals," Chemical Abstract database. (Publication date unknown.)		
JS	302	CHUNG et al. "Uptake, Degradation, and Release of Fibrillar and Soluble Forms of Alzheimer's Amyloid $\beta$ -Peptide by Microglial Cells," <u>J. Biol. Chem.</u> , 274(45):32301-32308 (1999).		
JS	291	COLOMA et al., "Transport Across the Primate Blood-Brain Barrier of a Genetically Engineered Chimeric Monoclonal Antibody to the Human Insulin Receptor," <u>Pharm. Res.</u> , 17:266-274 (2000).		
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X	220	Dialog/Derwent, Abstract of WPI Acc No: 1997-054436/199706: Stable vaccine compsns. - comprise a macrocyclic lactone, a milbemycin, an avermectin, an antigen, a dispersing agent, an adjuvant, a water sol. organic solvent and saline or water, Derwent File 351: Derwent WPI database. (Publication date unknown.)		
JS	288	DUMERY et al., " $\beta$ -Amyloid protein aggregation: its implication in the physiopathology of Alzheimer's disease," <u>Pathol. Biol.</u> , 49:72-85 (2001).		
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Examiner Signature		Date Considered	10-7-02
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Sheet 3 of 6

## **Complete if Known**

Application Number	09/580,015
Filing Date	May 26, 2000
First Named Inventor	Dale B. Schenk
Group Art Unit	1647
Examiner Name	Turner, Sharon L.
Attorney Docket Number	15270J-004750US

## **OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	226	Elan, "Elan and Wyeth Provide Update on Status of Alzheimer's Collaboration," Press Release (3/1/2002).	
	289	ESIRI, "Is an effective immune intervention for Alzheimer's disease in prospect?," <u>Trends in Pharm. Sci.</u> , 22:2-3 (2001).	
	246	FRENKEL et al., "Generation of auto-antibodies towards Alzheimer's disease vaccination," <u>Vaccine</u> , 19:2615-2619 (2001).	
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	251	GARDELLA et al., "Intact Alzheimer amyloid precursor protein (APP) is present in platelet membranes and is encoded by platelet mRNA," <u>Biochem. Biophys. Res. Comm.</u> , 173:1292-1298 (1990).	
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	253	GIULIAN, et al., "The HHQK Domain of b-Amyloid Provides a Structural Basis for the Immunopathology of Alzheimer's Disease," <u>Journal of Biological Chem.</u> , 273:29719-29726 (1998).	
	303	GONZALES-FERNANDEZ et al., "Low antigen dose favors selection of somatic mutants with hallmarks of antibody affinity maturation," <u>Immunology</u> , 93:149-153 (1998).	
	237	GORTNER, <u>Outlines of Biochemistry</u> , pp. 322-323, John Wiley & Sons, Inc., New York (1949).	
	254	GRUBECK-LOEBENSTEIN, et al., "Immunization with $\beta$ -amyloid: could T-cell activation have a harmful effect?," <u>TINS</u> , 23:114 (2000).	
	241	HAASS et al. "Amyloid beta-peptide is produced by cultured cells during normal metabolism," <u>Nature</u> , 359(6393):322-5 (1992).	

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				Filing Date	May 26, 2000
				First Named Inventor	Dale B. Schenk
				Group Art Unit	1647
				Examiner Name	Turner, Sharon L.
Sheet	4	of	6	Attorney Docket Number	15270J-004750US

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	255	HARIGAYA, et al., "Modified amyloid $\beta$ protein ending at 42 or 40 with different solubility accumulates in the brain of Alzheimer's disease," <u>Biochem. Biophys. Res. Comm.</u> , 211:1015-1022 (1995).		
	229	HAZAMA, et al., "Intranasal Immunization Against Herpes Simplex Virus Infection by Using a Recombinant Glycoprotein D Fused With Immunomodulating Proteins, the B Subunit of Escherichia Coli Heat-Labile Enterotoxin and Interleukin-2", <u>Immunology</u> , Vol. 78: 643-649 (1993).		
	236	HILBICH et al., "Human and rodent sequence analogs of Alzheimer's amyloid $\beta$ A4 share similar properties and can be solubilized in buffers of pH 7.4," <u>Eur. J. Biochem.</u> , 201:61-69 (1991).		
	256	IKEDA, et al., "Immunogold labeling of cerebrovascular and neuritic plaque amyloid fibrils in Alzheimer's disease with an anti- $\beta$ protein monoclonal antibody," <u>Lab. Invest.</u> , 57:446-449 (1987).		
	257	JEN, et al., "Preparation and purification of antisera against different regions or isoforms of b-amyloid precursor protein," <u>Brain Research Protocols</u> , 2:23-30 (1997).		
	258	KIDA, et al., "Early amyloid- $\beta$ deposits show different immunoreactivity to the amino- and carboxy-terminal regions of b-peptide in Alzheimer's disease and Down's syndrome brain," <u>Neuroscience Letters</u> , 193:105-108 (1995).		
	259	LANSBURY, PETER T., "Inhibition of amyloid formation: a strategy to delay the onset of Alzheimer's disease," <u>Curr. Ops. in Chemical Biology</u> , 1:260-267 (1997).		
	260	LEMERE, et al., "Nasal A $\beta$ treatment induces anti-A $\beta$ antibody production and decreases cerebral amyloid burden in PD-APP mice," <u>Annals of the NY Acad. Sci.</u> , 920:328-331 (2000).		
	261	MAK, et al., "Polyclonals to b-amyloid (1-42) identify most plaque and vascular deposits in Alzheimer cortex, but not striatum," <u>Brain Research</u> , 667:138-142 (1994).		
	263	MANN, et al., "Amyloid $\beta$ protein (A $\beta$ ) deposition in chromosome 14-linked Alzheimer's disease: Predominance of A $\beta$ <sub>42(43)</sub> ," <u>Annals of Neurology</u> , 40:149-156 (1996).		
	262	MANN, et al., "The extent of amyloid deposition in brain in patients with Down's syndrome does not depend upon the apolipoprotein E genotype," <u>Neuroscience Letters</u> , 196:105-108 (1995).		
	264	McGeer, et al., "Immunohistochemical localization of beta-amyloid precursor protein sequences in Alzheimer and normal brain tissue by light and electron microscopy," <u>J. of Neuroscience Res.</u> , 31:428-442 (1992).		
	238	MCNEAL et al., "Stimulation of local immunity and protection in mice by intramuscular immunization with triple- or double-layered rotavirus particles and QS-21," <u>Virology</u> , 243:158-166 (1998).		
	265	Mena, et al., "Monitoring pathological assembly of tau and $\beta$ -amyloid proteins in Alzheimer's disease," <u>Acta Neuropathol.</u> , 89:50-56 (1995).		
	233	MORRIS, et al., "The Consortium to Establish a registry for Alzheimer's Disease (CERAD)," <u>Neurology</u> , 39:1159-65 (1989).		

Examiner Signature		Date Considered	10-7-02
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 6

Complete if Known

Application Number 09/580,015  
Filing Date May 26, 2000  
First Named Inventor Dale B. Schenk  
Group Art Unit 1647  
Examiner Name Turner, Sharon L.  
Attorney Docket Number 15270J-004750US

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## OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
JS	250	NAKAMURA et al., "Histopathological studies on senile plaques and cerebral amyloid angiopathy in aged cynomolgus monkeys," <u>Exp. Anim.</u> , 43:711-718 (1995).	
JS	268	NAKAMURA, et al., "Carboxyl end-specific monoclonal antibodies to amyloid $\beta$ protein ( $A\beta$ ) subtypes ( $A\beta$ 40 and $A\beta$ 42(43)) differentiate $A\beta$ in senile plaques and amyloid angiopathy in brains of aged cynomolgus monkeys," <u>Neuroscience Letters</u> , 201:151-154 (1995).	
JS	281	NAKAYAMA et al., "Histopathological studies of senile plaques and cerebral amyloidosis in cynomolgus monkeys," <u>J. of Med. Primatology</u> , 27:244-252 (1998).	
JS	235	NEWCOMBE and COHEN, "Solubility characteristics of isolated amyloid fibrils," <u>Biochim. Biophys. Acta</u> , 104:480-486 (1965).	
JS	280	PARDRIDGE et al., "Chimeric peptides as a vehicle for peptide pharmaceutical delivery through the blood-brain barrier," <u>Biochem. Biophys. Res. Comm.</u> , 146:307-313 (1987).	
JS	232	PETERSON, et al., "Recombinant Antibodies: Alternative Strategies for Developing and Manipulating Murine-Derived Monoclonal Antibodies," <u>Laboratory Animal Science</u> , 46(1):8-14 (1996).	
JS	269	PHILIPPE, et al. "Generation of a monoclonal antibody to the carboxy-terminal domain of tau by immunization with the amino-terminal domain of the amyloid precursor protein," <u>J. of Neuroscience Res.</u> , 46:709-719 (1996).	
JS	279	SAITO et al., "Vector-mediated delivery of <sup>125</sup> I-labeled $\beta$ -amyloid peptide $Ab^{1-40}$ through the blood-brain barrier and binding to Alzheimer disease amyloid of the $A\beta^{1-40}$ vector complex," <u>PNAS USA</u> , 92:10227-10231 (1995).	
JS	278	SAITOH, N. and K. IMAI, "Immunological analysis of Alzheimer's disease using anti- $\beta$ -protein monoclonal antibodies," <u>Sapporo Med. J.</u> , 60:309-320 (1991).	
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JS	270	SCHENK, et al., " $\beta$ -peptide immunization," <u>Arch. Neurol.</u> , 57:934-936 (2000).	
JS	271	ST. GEORGE-HYSLOP, PETER H. and DAVID A. WESTAWAY, "Antibody clears senile plaques," <u>Nature</u> , 40:116-117 (1999).	
JS	272	SZENDREI, et al., "The effects of aspartic acid-bond isomerization on <i>in vitro</i> properties of the amyloid $\beta$ -peptide as modeled with N-terminal decapeptide fragments," <u>Int. J. Peptide Protein Res.</u> , 47:289-296 (1996).	
JS	273	THORSETT, E.D. and L.H. LATIMER, "Therapeutic approaches to Alzheimer's disease," <u>Curr. Op. in Chem. Biology</u> , 4:377-382 (2000).	
JS	276	TJERNBERG et al., "Arrest of $\beta$ -amyloid fibril formation by a pentapeptide ligand," <u>Journal of Biological Chemistry</u> , 271:8545-8548 (1996).	

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Substitute for form 1449A/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	09/580,015
		Filing Date	May 26, 2000
		First Named Inventor	Dale B. Schenk
		Group Art Unit	1647
		Examiner Name	Turner, Sharon L.
Sheet 6 of 6	Attorney Docket Number	15270J-004750US	

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JS	274	WEINER et al., "Nasal administration of amyloid- $\beta$ peptide decreases cerebral amyloid burden in a mouse model of Alzheimer's disease," <i>Annals of Neurology</i> , 48:567-579 (2000).	
X	223	Wisconsin Alumni Research Foundation, "Injection of Newborn Mice with Seven Chemical Adjuvants to Help Determine Their Safety in Use in Biologicals", U.S. Govt. Res. Develop. Rep., 70(24), 56. (Publication date unknown.)	
JS	275	WU, et al., "Drug targeting of a peptide radiopharmaceutical through the primate blood-brain barrier in vivo with a monoclonal antibody to the human insulin receptor," <i>J. Clin. Invest.</i> , 100:1804-1812 (1997).	
JS	292	YAMAGUCHI et al., Diffuse plaques associated with astroglial amyloid $\beta$ protein, possibly showing a disappearing stage of senile plaques," <i>Acta Neuropathol.</i> , 95:217-222 (1998).	
JS	290	YOUNKIN, "Amyloid $\beta$ vaccination: reduced plaques and improved cognition," <i>Nature Medicine</i> , 7:18-19 (2001).	

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FORM PTO-1449 (Modified)		Attorney Docket No.: 15270J-004750US		Application No.: 09/580,015	
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: DALE B. SCHENK			
		Filing Date: May 26, 2000		Group: 1641	
Reference Designation		U.S. PATENT DOCUMENTS			
Examiner Initial	Document No.	Date	Name	Class	Sub-class
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	Document No.	Date	Country	Class	Sub-class
AA	EP 613 007	8/31/94	Europe		
AB	WO 95/11994	5/4/95	PCT		
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)					
AC	Schenk et al., "Immunization with amyloid- $\beta$ attenuates Alzheimer-disease-like pathology in the PDAPP mouse," <i>Nature</i> , 400:173-177 (1999).				
AD	Van Gool et al., "Concentrations of amyloid- $\beta$ protein in cerebrospinal fluid increase with age in patients free from neurodegenerative disease," <i>Neuroscience Letters</i> , 172:122-124 (1994).				
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